Complete Summary

GUIDELINE TITLE

Osteoporosis.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Osteoporosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2004 Jan. 14 p. (ACOG practice bulletin; no. 50). [78 references]

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Osteoporosis

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To discuss appropriate screening strategies and significant pharmacologic interventions available to prevent and treat osteoporosis

TARGET POPULATION

- Adult women (counseling, screening)
- Postmenopausal women with or at risk of developing osteoporosis (prevention, treatment)

INTERVENTIONS AND PRACTICES CONSIDERED

Screening

1. Bone mineral density testing using dual-energy x-ray absorptiometry (DXA)
2. Peripheral bone densitometry using quantitative ultrasonography, single-energy X-ray absorptiometry, peripheral DXA, and peripheral quantitative computed tomography
3. Biochemical markers of bone turnover

Prevention

1. Counseling regarding lifestyle change including weight-bearing and muscle strengthening exercises, adequate calcium consumption, adequate vitamin D consumption, smoking cessation, moderation of alcohol consumption and fall prevention strategies
2. Pharmacotherapy, including estrogen, bisphosphonates (alendronate and risendronate), and raloxifene

Treatment

1. Estrogen
2. Bisphosphonates (alendronate and risendronate)
3. Selective estrogen receptor modulators (currently only raloxifene is available)
4. Salmon calcitonin
5. Human recombinant parathyroid hormone (PTH)

6. Combination therapy
7. Treatment initiation and monitoring

MAJOR OUTCOMES CONSIDERED

- Bone mineral density
- Fracture rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and October 2003. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician–gynecologists were used.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I: Evidence obtained from at least 1 properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than 1 center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

Guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Treatment should be initiated to reduce fracture risk in postmenopausal women who have experienced a fragility or low-impact fracture.
- Treatment should be instituted in those postmenopausal women with bone mineral density T scores less than -2 by central dual-energy x-ray absorptiometry (DXA) in the absence of risk factors and in women with T scores less than -1.5 in the presence of 1 or more risk factors.
- First-line pharmacologic options determined by the U.S. Food and Drug Administration (FDA) to be safe and effective for osteoporosis prevention (bisphosphonates [alendronate and risedronate], raloxifene, and estrogen) should be used.
- First-line pharmacologic options determined by the FDA to be safe and effective for osteoporosis treatment (bisphosphonates [alendronate and risedronate], raloxifene, calcitonin, and parathyroid hormone [PTH]) should be used.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Women should be counseled about the following preventive measures:
    - Adequate calcium consumption, using dietary supplements if dietary sources are not adequate
    - Adequate vitamin D consumption (400 to 800 IU daily) and the natural sources of this nutrient
    - Regular weight-bearing and muscle-strengthening exercises to reduce falls and prevent fractures
    - Smoking cessation
    - Moderation of alcohol intake
    - Fall prevention strategies

- Bone mineral density testing should be recommended to all postmenopausal women aged 65 years or older.
- Bone mineral density testing may be recommended for postmenopausal women younger than 65 years who have 1 or more risk factors for osteoporosis (see box "Risk Factors for Osteoporotic Fracture in Postmenopausal Women," below).
- Bone mineral density testing should be performed on all postmenopausal women with fractures to confirm the diagnosis of osteoporosis and determine disease severity.
- In the absence of new risk factors, screening should not be performed more frequently than every 2 years.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Women should be counseled on the risks of osteoporosis and related fragility fractures. Such counseling should be part of the annual gynecologic examination.

Table. Risk Factors for Osteoporotic Fracture in Postmenopausal Women

- History of prior fracture
- Family history of osteoporosis
- Caucasian race
- Dementia
- Poor nutrition
- Smoking
- Low weight and body mass index
- Estrogen deficiency*
    - Early menopause (age younger than 45 years) or bilateral oophorectomy
    - Prolonged premenopausal amenorrhea (>1 year)
- Long-term low calcium intake
- Alcoholism
- Impaired eyesight despite adequate correction
- History of falls
- Inadequate physical activity

*A patient's current use of hormone therapy does not preclude estrogen deficiency.

Data from Osteoporosis prevention, diagnosis, and therapy. NIH Consens Statement 2000;17(1):1-45.

Definitions:

Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial

II-1: Evidence obtained from well-designed controlled trials without randomization

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendation

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening, prevention, and treatment of osteoporosis

POTENTIAL HARMS

- When estrogen or hormone therapy is discontinued, bone turnover increases and bone loss tends to accelerate.
- Although the risks of long-term use of estrogen or hormone therapy are small, many recommend such therapy be used for the shortest period at the lowest possible dose. The Women's Health Initiative study indicated a

significantly increased risk of cardiovascular events and breast cancer for women taking combined estrogen and progestin therapy.
- Bisphosphonates may cause upper gastrointestinal side effects
- Although generally well tolerated, side effects of raloxifene include vasomotor symptoms (hot flashes and night sweats). It also has risks (deep vein thrombosis and pulmonary embolism) similar to those of estrogens.
- Calcitonin is generally well tolerated. Its side effects are nausea, local inflammation (injection), flushing of the face or hands (injection), and nasal irritation (nasal spray).
- Parathyroid hormone treatment is expensive and requires daily injections.

CONTRAINDICATIONS

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Bisphosphonates are contraindicated in individuals with reflux, gastroesophageal reflux disease, and other esophageal abnormalities.

QUALIFYING STATEMENTS

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These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Foreign Language Translations
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Osteoporosis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2004 Jan. 14 p. (ACOG practice bulletin; no. 50). [78 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Jan

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Osteoporosis. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2003.

Electronic copies: Available from the American College of Obstetricians and Gynecologists (ACOG) Web site. Copies are also available in Spanish.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

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NGC STATUS

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